REMARKS

The present communication responds to the Office Action of May 13, 2005. In that Office Action, the Examiner rejected each of the pending claims. The rejections are respectfully traversed for the reasons explained below and reconsideration and allowance are requested

Rejection under 35 U.S.C. § 102(b)

Korf et al.

Claims 30, 31, 33 and 35-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,013,029 to Korf et al. This rejection is traversed at least for the following reasons.

Korf et al. disclose a method and device for monitoring the concentration of a substance in a body fluid. The device comprises an interface held in contact with a living human or animal body and a detector positioned downstream from the interface. A profusion fluid is passed from the interface to and along the detector at a flow rate of less than 60 μl/hour. The layout of the Korf et al. device is illustrated in Figures 8, 9, and 10. Generally, the device comprises a housing 38 having the size of a wrist-watch. The housing includes a membrane 29 which is placed against the skin:

> The device comprises a supply reservoir 6, a waste reservoir 5 filled with fluid absorbing material, a conduit 4 extending between the supply reservoir 6 and the waste reservoir 5 and an interface in the form of a membrane 29 behind which a portion 30 of the conduit extends. The membrane 29 is to be placed against the skin, substances in the body of the patient pass through the membrane 29, into the part 30 of the conduit 4 behind the membrane 29 and are entrained by passing perfusion fluid. After passing the part 30 of the conduit 4 behind the membrane 29, the perfusion fluid is treated by the preoxidator 8, passed through the selector 7 and a monitoring signal depending on the flux of a substance coming from the selector 7 is generated by the detector 3. *Korf et al., Column 15, line 63 – Column 16, line 8.*

Thus, Korf et al. disclose a device having a membrane which is placed against the skin, not a device including an implantable access portion.

In an alternate embodiment, the Korf et al. device may be positioned in a catheter:

> FIG. 5 shows a pick-up and detection module of a device according to the invention, which is incorporated in a catheter. Since a catheter is generally not maintained in the body of the patient for a very long time and the flow rate of the method according to the invention is very low, the detector 3 as well as the supply and the waste reservoirs 6 and 5, respectively, can be very compact so that these parts can be located in the catheter and supply and return conduits extending along the catheter are not needed. Moreover, a very quick response of the detector 3 is achieved since the detector 3 can be positioned very close to the interface 2. The embodiment shown in FIG. 5 is also provided with a preoxidator 8 and a selector 7. Also these parts of the device can be made sufficiently compact to be positioned within the catheter due to the low flow rate of the method according to the invention and the correspondingly low capacity requirements these parts have to fulfil. *Korf et al., Column 12, lines 47-63.*

In the embodiment of Korf et al. wherein the device is positioned in a catheter, the detector is also located in the catheter. That embodiment does not provide an access portion implantable in the body and a sensor disposed outside of the body when the access portion is implanted in the body, as recited by claim 30.

The Korf et al. device is designed to be an independent functional unit:

> The device according to FIG. 1 further comprises a waste reservoir 5 and a supply reservoir 6 so that it can function completely independently of any stationary support devices. Instead of leading used perfusate to a waste reservoir, it may also simply be emitted out of the device.

Accordingly, the Korf et al. device includes a waste reservoir and a supply reservoir and not an inlet portion or an outlet portion.

Korf et al. do not disclose a device comprising "a structure having *an inlet portion, an access portion, and an outlet portion, the access portion being implantable in the body* when the device measures the fluids in the body and being in fluid communication between the inlet portion and the outlet portion, wherein the access portion has a fluid channel in which a dialysis fluid flows from the inlet portion to the outlet portion whereby constituents of the fluids in the

body are picked up by the dialysis fluid flowing through the access portion; and a sensor being arranged in the fluid channel in vicinity of the outlet portion, *the sensor being disposed outside of the body when the access portion is implanted in the body* to measure the fluids in the body," as recited by claim 30.

Accordingly, it is respectfully submitted that Korf et al. do not anticipate claim 30. As each of claims 31, 33, and 35-37 depend from claim 30, it is further submitted that Korf et al. do not anticipate any of these claims. Reconsideration and allowance of claims 30, 31, 33, and 35-37 are thus respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Korf et al. in view of Say

Claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Korf et al. in view of Say 6,128,51. This rejection is traversed at least for the following reasons.

As discussed above, it is respectfully submitted that Korf et al. do not disclose each of the elements recited in claim 30. Say teaches a sensor assembly including a catheter having a catheter sheath adapted for insertion in a patient. Say fails to disclose or teach the above discussed features as recited in claim 30. Accordingly, it is respectfully submitted that Say does not correct the fundamental deficiencies of Korf et al.

The applicants respectfully submit that neither Korf et al. nor Say, alone or in combination, make obvious the device of claim 32. Reconsideration and allowance of claim 32 are thus respectfully requested.

Korf et al. in view of Pfeiffer et al.

Claim 34 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Korf et al in view of Pfeiffer et al. 5,640,954. This rejection is traversed at least for the following reasons.

As discussed above, it is respectfully submitted that Korf et al. do not disclose each of the elements recited in claim 30. Pfeiffer et al. teach a method and apparatus for continuously

monitoring the concentration of a metabolyte. The apparatus comprises a microdioaysis probe implanted in the body and a measuring device positioned outside of the body:

> The apparatus for monitoring metabolite concentrations in bodily tissue according to FIG. 1 consists primarily of a microdialysis probe 18 implanted into subcutaneous tissue 10 of a patient and a measuring device 28 positioned outside of the body, in which the microdialysis probe 18 subjected to a perfusion fluid flow at the inlet side by way of a perfusion fluid tube 12, communicates with a flow chamber 16 at the outlet side by way of a dialysate tube 14 and a measuring dialysate tube 15, a sensor 26 of the measuring device 28 is coupled to flow chamber 16, and in which a feed channel 22 of an enzyme solution reservoir 24 is connected inbetween dialysate tube 14 and measuring dialysate tube 15 at a junction 20. *Pfeiffer et al., Column 4, lines 43-55.*

The measuring dialysate flow is transported to the flow chamber 16 a through a tube 15 by way of junctions 40, 42 and then is led pas a sensor 26 of the measuring device 28:

> The measuring dialysate flow is led through the flow chamber 16 which is interconnected in the measuring dialysate tube 15 by way of junctions 40, 42, the measuring dialysate flow is led past sensor 26 and is finally led into a receptacle 44 which is positioned after second transport means 36 in order to be disposed of at a later time. *Pfeiffer et al., Column 5, lines 2-8.*

Pfeiffer et al. do not correct the fundamental teaching deficiencies of Korf et al. At least, neither Korf et al. nor Pfeiffer et al. disclose, teach, or suggest, "a sensor being arranged in the fluid channel in vicinity of the outlet portion," as recited by claim 30.

Accordingly, it is respectfully submitted that neither Korf et al. nor Pfeiffer et al., alone or in combination, make obvious the device of claim 34. Reconsideration and allowance of claim 34 are thus respectfully requested.

Conclusion

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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